DETAILED ACTION

1.   **THE FINALITY OF THE LAST OFFICE ACTION IS HEREBY VACATED.**

2.   Applicants' Response to Final Office Action, received 13 August 2009, is acknowledged.

Claims 11, 15, 17, 19 and 22 have been amended.

3.   Claims 11-25 are pending and under consideration.

Rejections Withdrawn

4.   The rejection of claims 15, 16 and 18-21 under 35 U.S.C. 112, second paragraph, as

being indefinite for identity of "antigen", is withdrawn in light of the amendment of the claims.

5.   The rejection of claims 17 and 22-25 under 35 U.S.C. 112, second paragraph, as being

indefinite for identity of "antigen", is withdrawn in light of the amendment of the claims.

6.   The rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being indefinite for

identity of claimed invention, is withdrawn in light of the amendment of the claim.

Examiner Inquiry

7.   The Examiner requests clarification on the name of co-inventor Ram Pramod Tiwary of

Gwalior, INDIA. Several printed references spell the last name as "Tiwari", e.g., J. Clin. Lab.

Anal., Vol. 17, pages 155-163, 2003, and Int. J. Tuberc. Lung Dis., Vol. 11(10), pages 1143-

1151, 2007.

Claim Objections

8.   Claim 11 is objected to because of the following informalities: lines 5 and 6,

"*Mycobacterial*" should be "*Mycobacterium*" for consistency with the rest of the specification

and claims. Appropriate correction is required.

9.   Claim 15 is objected to because of the following informalities: lines 4 and 6,

"*Mycobacterial*" should be "*Mycobacterium*" for consistency with the rest of the specification

and claims. Appropriate correction is required.

10.   Claim 18 is objected to because of the following informalities: line 3,

"phophotidylcholine" should be "phosphatidylcholine". Appropriate correction is required.

11.   Claim 23 is objected to because of the following informalities: lines 2 and 3,

"*Mycobacterial*" should be "*Mycobacterium*" for consistency with the rest of the specification

and claims. Appropriate correction is required.

12.   Claim 25 is objected to because of the following informalities: line 3, "H37Rv" should be

"$H_{37}Rv$". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13.   Claims 11-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite

for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention.

        Claim 11 recites in lines 4-5, "an anti-mycobacterial glycolipid antibody from

Mycobacterial tuberculosis". It is unclear how one obtains an antibody from the bacterium. It

is recommended that the phrase be "an antibody which binds glycolipid from *Mycobacterium*

tuberculosis".

Claims 12-14 depend from claim 1, but do not clarify the issue.

Claim 15 recites in lines 3-4, "an anti-mycobacterial glycolipid antibody from

Mycobacterial tuberculosis". It is unclear how one obtains an antibody from the bacterium. It

is recommended that the phrase be "an antibody which binds glycolipid from *Mycobacterium*

tuberculosis".

Claims 16-25 depend from claim 15, but do not clarify the issue.

14.   Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for

failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention.

Claim 14 depends from claim 11 and is therefore a diagnostic kit for detecting

pulmonary and extra pulmonary tuberculosis utilizing a glycolipid from *M. tuberculosis* $H_{37}Rv$.

The positive control comprises an antibody against glycolipid from *M. tuberculosis.*

However, claim 14 recites that the positive control is prepared by immunizing a rabbit

with "mycobacterium antigens". There is no restriction that the "mycobacterium antigens"

comprise any glycolipid nor that the antigens are from *M. tuberculosis*. Thus, is it unclear how

one obtains an antibody with the necessary binding characteristics if the "mycobacterium

antigens" are from, e.g., *M. scrofulaceum*, or contain no glycolipids.

Conclusion

15.   No claims are allowed.

16.   Any inquiry concerning this communication or earlier communications from the Examiner

should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)

272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00

AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the

Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is

assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

August 27, 2009